# In the United States Court of Federal Claims

### **OFFICE OF SPECIAL MASTERS**

No. 16-307V Filed: June 27, 2017 Not for Publication

MILLMAN, Special Master

## **DECISION**<sup>1</sup>

On March 9, 2016, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that within 45 minutes of receiving tetanus-diphtheria-acellular pertussis ("Tdap") vaccine on March 13, 2013, she had severe headache, shortness of breath, decreased blood pressure, and "air hunger." Pet. at ¶ 5. She alleged on-Table anaphylaxis and on-Table brachial neuritis. Pet. Preamble. In the alternative, petitioner alleged an immune-mediated inflammatory condition resulting in pain, tightness and weakness in her left arm, shoulder and chest, aggravated ongoing environmental allergies, and increased sensitivity to environmental and chemical irritants. Id.

<sup>&</sup>lt;sup>1</sup> Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

On March 9, 2016, the case was assigned to the Special Processing Unit ("SPU").

On July 11, 2016, petitioner filed as Statement of Completion of the record.

On October 17, 2016, respondent filed his Rule 4(c) Report, recommending against compensation principally because petitioner did not have anaphylaxis or brachial neuritis. Resp't's Rep. at 4, 7, 10, 11.

On October 26, 2016, the Chief Special Master transferred this case to the undersigned.

On November 22, 2016, the undersigned issued an Order giving petitioner until January 23, 2017 to file an expert report, noting that the medical records did not support her allegations of anaphylaxis and brachial neuritis. Moreover, petitioner's assertions of subsequent injuries rested upon her having had an initial allergic reaction to Tdap vaccine without which, there was no predicate for these injuries.

On January 20, 2017, petitioner moved for an extension of time of 60 days to file an expert report, which the undersigned granted.

On March 27, 2017, petitioner made a second motion for an extension of time for another 60 days to file an expert report, which the undersigned granted.

On May 26, 2017, petitioner made a third motion for an extension of time for 30 days to file an expert report, which the undersigned granted.

On June 26, 2017, petitioner filed a motion for a status conference to discuss how to proceed in light of the fact that petitioner's two retained expert immunologists could not write an expert report in support of causation. The undersigned granted petitioner's motion and held a status conference on June 27, 2017.

During that status conference, petitioner made an oral motion for a decision dismissing the petition because she was unable to meet her burden of proof. The undersigned **GRANTS** petitioner's motion and **DISMISSES** this case for failure to prove she had a Table injury or, in the alternative, causation in fact injuries.

## **Medical Records**

On March 22, 2014, petitioner saw Dr. Scott Cameron who tested her for allergies to egg, milk and Tdap, with the results being negative to all three and the rest of the aeroallergens. Med. recs. Ex. 5, at 4.

On June 11, 2013, petitioner underwent an EMG, the results of which were normal except for mild carpal tunnel syndrome in her left hand, but negative for neurologic pathology such as brachial neuritis. Med. recs. Ex. 11, at 31.

On December 29, 2013, Dr. Wayne Shytbel, a neurologist, examined petitioner and found she was normal neurologically with no evidence of neuropathy or myopathy. Med. recs. Ex. 11, at 25.

In February 2015, petitioner underwent another EMG, the results of which were consistent with the EMG she underwent in June 2013, i.e., they were normal. Med. recs. Ex. 8, at 9.

#### **DISCUSSION**

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." <u>Grant</u>, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. <u>Id.</u> at 1148.

Petitioner must show not only that but for her Tdap vaccination, she would not have anaphylaxis and brachial neuritis, but also that her Tdap vaccination was a substantial factor in causing anaphylaxis and brachial neuritis. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). She can hardly prove that Tdap vaccine caused her anaphylaxis (not even mentioning the requirement that the vaccine injury last more than six months) or brachial neuritis when she does not have either.

The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion. No medical records show that petitioner had an adverse reaction to Tdap vaccine which lasted more than six months. Petitioner has not filed a medical expert report in support of her allegations.

This petition is **DISMISSED**.

#### **CONCLUSION**

The petition is **DISMISSED** for failure to make a prima facie case. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.<sup>2</sup>

IT IS SO ORDERED.

Dated: June 27, 2017 /s/ Laura D. Millman Laura D. Millman

Special Master

<sup>&</sup>lt;sup>2</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.